

### **REMARKS**

The above-identified application has been reviewed in light of the Final Office Action mailed October 21, 2011. No amendments to the claims are being submitted herewith. Claims 1-24, 26 and 30 had previously been cancelled, so claims 25 and 27-29 are currently pending and under consideration. Applicant submits that the claims pending in this application are allowable over the cited references of record. Reconsideration and allowance of the present application is respectfully requested.

### **Rejection Under 35 U.S.C. § 103**

In the Office Action, the Examiner rejected claims 25 and 27-29 under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication No. 2002/0090339 to Whalen et al. (hereinafter "Whalen") in view of U.S. Patent Application Publication No. 2004/0224864 to Patterson et al. (hereinafter "Patterson"), or U.S. Patent Application Publication No. 2004/0197302 to Porter et al. (hereinafter "Porter"). The rejections were maintained for reasons of record in the previous office actions. Applicant respectfully disagrees because an obviousness rejection under 35 U.S.C. § 103 requires a suggestion of *all limitations* in a claim, In re Wanda and Murphy, Appeal 2007-3733 (B.P.A.I. Jan. 2008), and the references fail to disclose, teach or suggest several limitations.

More specifically, while Whalen teaches embolic compositions including a biocompatible polymer, a biocompatible contrast agent, and a biocompatible solvent, nowhere does Whalen teach or suggest a composition consisting of up to 40 weight percent of ethylene vinyl alcohol

copolymer; dimethylsulfoxide; and from 45 to no more than 60 weight percent of tantalum contrast agent having an average particle size of about 5 microns or less, wherein the ratio of ethylene vinyl alcohol copolymer to the tantalum contrast agent is from 0.077 to 0.90 and the weight percent of each component is based on the total weight of the composition, and further wherein said composition has a viscosity of 150 cSt or higher at 40°C, as recited in claim 25.

Whalen does not teach the use of a contrast agent in an amount from 45 to no more than 60 weight percent in the composition.

Neither Patterson nor Porter remedy the deficiencies of Whalen, no matter how these references may be combined. While Patterson discloses a composition of a biocompatible polymer, a contrast agent, and fumed silica (a rheology modifier), nowhere does Patterson teach or suggest a composition consisting of up to 40 weight percent of ethylene vinyl alcohol copolymer; dimethylsulfoxide; and from 45 to no more than 60 weight percent of tantalum contrast agent having an average particle size of about 5 microns or less, wherein the ratio of ethylene vinyl alcohol copolymer to the tantalum contrast agent is from 0.077 to 0.90 and the weight percent of each component is based on the total weight of the composition, and further wherein said composition has a viscosity of 150 cSt or higher at 40°C, as recited in claim 25.

Similarly, while Porter teaches a rheologically-modified composition comprising a solution including a biocompatible prepolymer, a contrast agent, and a rheological modifier, nowhere does Porter teach or suggest a composition consisting of up to 40 weight percent of ethylene vinyl alcohol copolymer; dimethylsulfoxide; and from 45 to no more than 60 weight

percent of tantalum contrast agent having an average particle size of about 5 microns or less, wherein the ratio of ethylene vinyl alcohol copolymer to the tantalum contrast agent is from 0.077 to 0.90 and the weight percent of each component is based on the total weight of the composition, and further wherein said composition has a viscosity of 150 cSt or higher at 40°C, as recited in claim 25.

The difficulties of maintaining a proper viscosity in compositions with elevated levels of contrast agent are described in the specification of the instant application as follows (references are to the paragraph numbers found in the published patent application, U.S. Patent Application Publication No. 2004/0228797):

[0019] With regard to the above, the art has disclosed the use of up to 40 weight percent of the contrast agent into the embolic composition.<sup>1,2</sup> However, the mere addition of additional contrast agent into the embolic composition in order to enhance fluoroscopic visibility poses several practical concerns.

[0020] One practical concern is that of ensuring the embolic composition is suited for microcatheter injection, as embolic compositions are typically delivered through microcatheters. Accordingly, the quantity of water-insoluble biocompatible contrast agent suspended in the composition must result in a composition with adequate flowability through the microcatheter. That is to say that the contrast agent cannot plug the microcatheter or cause high injection pressures.

[0021] Another practical concern is the level of embolization precision achieved with the embolic composition. The use of higher quantities of water-insoluble biocompatible contrast agent must result in a coherent precipitate formed in vivo which minimizes fragmentation and possible embolization of unintended vascular sites. It is believed that the cohesive precipitate formed is a matrix of water-insoluble contrast agent encapsulated within the

water-insoluble biocompatible polymer. Accordingly, higher amounts of water-insoluble contrast agent may not result in a cohesive precipitate particularly at low concentrations of polymer as found in embolic compositions having low viscosities, i.e., less than about 100 cSt at 40 C.

[0022] Yet another practical concern is that embolic compositions are delivered parenterally, including intravascular delivery. Due to the parenteral nature of delivery, the patient's filtering mechanisms, utilized with enteral delivery, are not available. As such, the embolic compositions as injected must not pose a danger to the patient. The use of higher quantities of water-insoluble biocompatible contrast agent must result in a composition whose population of large particles is small enough not to pose a health threat.

The cited references do not appreciate the difficulties which may arise with increased levels of contrast agent. Moreover, as previously noted, the only references that teach greater than 40 weight percent of water-insoluble contrast agent (Porter and Patterson) further employ a rheology modifier. The recited compositions **do not** include rheology modifiers. Thus, it is respectfully submitted that both Porter and Patterson, which teach the need for employing rheology modifiers in their compositions to obtain a proper viscosity, teach away from the recited composition, which provides for compositions having high amounts of contrast agent, without the need for rheology modifiers.

Accordingly, for at least the foregoing reasons, it is respectfully submitted that claim 25 is patentable over Whalen in view of Patterson and/or Porter, no matter how these references may be combined. Claims 27-29 depend from claim 25 and incorporate all of its limitations therein. Thus, for at least the reasons listed above with respect to claim 25, claims 27-29 are similarly

patentable over Whalen in view of Patterson and/or Porter. Accordingly, withdrawal of the rejection of claims 25 and 27-29 under 35 U.S.C. §103(a) is respectfully requested.

**Nonstatutory Obviousness Type Double Patenting**

Claims 25-30 were rejected on the ground of nonstatutory obviousness type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 5,667,767 and claims 1-8 and 16-23 of U.S. Patent No. 5,695,480. (Claims 25 and 27-29 are pending at this time.)

Applicants maintain that none of the cited references teach or suggest a contrast agent concentration of from 45 to no more than 60 weight percent. At best, the prior art teaches a maximum of about 40 weight percent tantalum. Furthermore, the art teaches that preferred embodiments use less than 40 weight percent tantalum. Such would teach away from the currently claimed range found in now presented Claim 25.

However, in the interest of advancing prosecution of the instant application, Applicants will consider filing a terminal disclaimer as to these references once all other issues of patentability are resolved.


Conclusion

Applicants submit that all of the pending claims have been addressed. However, the absence of a reply to a specific rejection, issue or comment does not signify agreement with or concession of that rejection, issue or comment. Should the Examiner believe that a telephone interview may facilitate resolution of any outstanding issues, the Examiner is respectfully requested to telephone Applicant's undersigned attorney at the number listed below.

In addition, because the arguments made above may not be exhaustive, there may be reasons for patentability of any or all pending claims (or other claims) that have not been expressed. Finally, nothing in this paper should be construed as an intent to concede any issue with regard to any claim, except as specifically stated in this paper, and the amendment of any claim does not necessarily signify concession of unpatentability of the claim prior to its amendment.

In consideration of the foregoing discussion, the subject application is believed to be in condition for allowance. Early allowance of the subject application is respectfully solicited.

Respectfully submitted,



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